K122289

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IMAGING SYSTEMS

Traditional 510(k) Summary

OCT 24 2012

- **Image-Com 5.0**

Owner's Name and Address
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person
B. Mumm
COO
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Common, Classification & Proprietary Names

Common Name:	Various Image Analysis System Software
Classification Name:	Picture archiving and communications system

Proprietary Name(s):

Image-Com 5.0

Predicate Devices

Predicate Device 1	K110667	Image-Arena Platform 4.5, Echo-Com 4.5, Image-Com 4.5
Predicate Device 2	K071232	Image-Arena Applications; Research-Arena Applications : 4D Cardio-View 2.x

Device Description

Image-Com is a clinical application package software for reviewing and measuring of digital medical data. Image-Com is either embedded in Image-Arena™ platform or can be integrated into Third Party platforms, such as PACS or CVIS.

Indications for use and Intended use

Image-Com software is intended for reviewing and measuring of digital medical data of different modalities. It can be driven by Image-Arena or other third party platforms and is intended to launch other commercially available analysis and quantification tools.

Technological Characteristics Comparison

The Subject Device "Image-Com 5.0" is a CAP for analysis of medical studies containing 2D, 3D or 4D images.
The actual submission combines the advantages of the FDA cleared software products:

Predicate Device 1	K110667	Image-Arena Platform 4.5, Echo-Com 4.5, Image-Com 4.5
Predicate Device 2	K071232	Image-Arena Applications; Research-Arena Applications : 4D Cardio-View 2.x

The Subject Device includes the main functionalities as provided from **Predicate Device 1** (Image-Com 4.6, TomTec Imaging Systems GmbH). The underlying technology of the Subject Device is identical to the predicate devices.
It is a combined version of the **Predicate Device 1** (Image-Com 4.5, TomTec Imaging Systems GmbH, for 2D analysis) and **Predicate Device 2** (Cardio-View 2.x, TomTec Imaging Systems GmbH, for 3D/4D analysis) allowing the users to perform 2D, 3D and 4D image analysis within one software package.

Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted.
The test procedure was performed according to the Project Quality Plan.
Test results were reviewed by designated technical professionals before software proceeded to release.
All requirements have been verified by tests or other appropriate methods.

The incorporated OTS Software is considered validated either by particular tests or implied by the absence of OTS SW related abnormalities during all other V&V activities.
The summary conclusions state that:

- all automated tests were reviewed and passed
- feature complete test completed without deviations
- functional tests are completed
- measurement verification is completed without deviations
- multilanguage tests are completed without deviations
- all non-verified bugs have been evaluated and are rated as minor deviations. They are deferred to the next release

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the device is as safe as effective, and performs as well as or better than the predicate devices.

A clinical evaluation following the literature route based on the assessment of benefits, associated with the use of the device, was performed. The clinical evaluation shows that the published data are relevant and applicable to the relevant characteristics of the device under assessment and the medical procedure for which the device is intended.

Risk analysis aspects were treated in the risk management report. Based on this document the existing applied methods in the literature and the newly described techniques of the product (which are considered in the risk analysis) were evaluated.
No further risks were identified.

Conclusion from the analysis of the literature review

- The Risk-Benefit Assessment that the Benefit is superior to the Risk. Whereas the Risk is low. The benefit of the product is improving the accuracy of assessment and analyze-time. The product Image-Com is therefore harmless for patient and user and the advantages overbalance the probable risks of injury or illness for the patient.
- The data are sufficient to demonstrate compliance with the essential requirements covering safety and performance of the device in question under normal conditions of use.
- The claims made in the device labeling are substantiated by the clinical data.

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Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the device is as safe as effective, and performs as well as or better than the predicate devices.

No reportable events or problems for the predicate devices exist.
The overall product concept was clinically accepted and the test results support the conclusion that the subject device is as safe as effective and performs as well as the predicate devices.

July 23, 2012

B. Mumm
COO

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2012

Mr. Bernhard MUMM
COO
TomTech Imaging Systems GmbH
Edisonstrasse 6
Unterschleissheim, Bavaria D-85716
GERMANY

Re: K122289
Trade/Device Name: Image-Com 5.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 23, 2012
Received: July 30, 2012

Dear Mr. MUMM:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

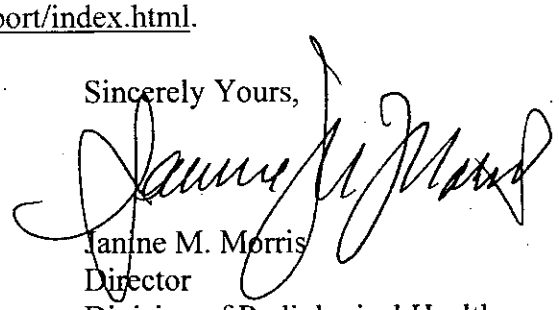
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122289

Device Name: Image-Com 5.0

Indications For Use:

Image-Com software is intended for reviewing and measuring of digital medical data of different modalities. It can be driven by Image-Arena or other third party platforms and is intended to launch other commercially available analysis and quantification tools.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K122289